510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:
k071067

B. Purpose for Submission:
New Device

C. Measurand:
Breath Alcohol

D. Type of Test:
Quantitative (Semiconductor Oxide Alcohol Sensor)

E. Applicant:
KHN Solutions, LLC

F. Proprietary and Established Names:
BACKTRACK™ Breathalyzer Digital Alcohol Detector

G. Regulatory Information:

1. Regulation section:
   21 CFR § 862.3050

2. Classification:
   Class I, reserved

3. Product code:
   DJZ

4. Panel:
   Toxicology (91)

H. Intended Use:

1. Intended use(s):
   Refer to Indications for use below.

2. Indication(s) for use:
   This device is intended to measure alcohol in human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.

3. Special conditions for use statement(s):
   Over-the-counter use

4. Special instrument requirements:
   BACTRACK breathalyzer

I. Device Description:

The BACTRACK™ Breathalyzer is designed to work with a simple one button operation. The BACTRACK™ Breathalyzer operates on two AA Alkaline batteries. The battery lasts for approximately 300 tests. There is a low battery which lights an LCD on the front panel when the voltage goes too low. The BACTRACK™ Breathalyzer sensor uses tin dioxide which has n-type conductivity when exposed to the atmosphere. This exposure causes a decrease in the number of electrons effecting absorbed oxygen molecules and thus increases resistance. If a specific gas (reducing gas) is presented, a reaction occurs with the absorbed oxygen which causes an increase in the electrons in the oxide molecules causing a decrease in resistance. This change in resistance can be measured and used to identify a specific gas (such as alcohol) and can be quantified into a % concentration.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   AlcoMate CA2000 Digital Alcohol Detector

2. Predicate 510(k) number(s):
   k041334

3. Comparison with predicate:

Feature	AlcoMate CA2000™ Digital Alcohol Detector, k041334	BACTRACK™ Breathalyzer
Indications For Use	This device is intended to measure alcohol in the human breath. Measurements obtained by this device are used as an aid in the detection of alcohol intoxication.	SAME
Mode	Breath Alcohol Concentration	SAME
Practitioner Use	Over the Counter	SAME
Blowing time	5 Seconds	SAME
Display	3 Digit LED	3 Digit LCD
Power Source	9 Volt Alkaline Battery or auto cigar lighter (Optional)	2 – AA Alkaline
Battery Life	300 Tests	SAME
Measurement Range	.00-.40%	SAME
Type Of Sensor	Semiconductor-Oxide Sensor	Semiconductor-Oxide Sensor
Anatomical Site	Mouth	SAME
Mouthpiece	Replaceable	No mouthpiece

Warm Up Time	20 seconds	10 Seconds
Dept of Transportation	DOT Approved	Meets DOT requirements
Construction	Plastic case with internal circuit board	SAME
Size	5" x 3 ¼" x 1.2"	4.25" x 1.63" x 0.81" (10.8 x 4.1 x 2.1 cm)
Weight	200 grams.	1.4 oz (39.7 grams)

K. Standard/Guidance Document Referenced (if applicable):

The sponsor states conformance to the following standards:

1. Department of Transportation National Highway Traffic Safety Administration [NHTSA Docket No. 94-004; Notice 2] Highway Safety Programs; Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids
2. IEC 60601-1, Safety of Medical Electrical Equipment, Part 1, General Requirements for Safety, including Amendment 1 and 2
3. EN 61000-6-3:2001+A11:2004 & EN 61000-6-3:2001. Electromagnetic compatibility (EMC)-part 6-3: Generic standards – Emission standard for residential, commercial and light industry environments.

L. Test Principle:

The BACTRACK™ Breathalyzer is designed to measure deep lung air to test for the presence of alcohol in the blood. The relationship between alcohol in the blood and alcohol in the deep lung breath is well established by Henry's law in a ratio of 2100:1 The BACTRACK™ Breathalyzer has been tested and uses a blow time of 5 seconds to capture an accurate deep lung sample. The BACTRACK™ Breathalyzer sensor uses tin dioxide which has n-type conductivity when exposed to the atmosphere. This exposure causes a decrease in the number of electrons affecting absorbed oxygen molecules and thus increases resistance. If a specific gas (reducing gas) is presented, a reaction occurs with the absorbed oxygen which causes an increase in the electrons in the oxide molecules causing a decrease in resistance. This change in resistance can be measured and used to identify a specific gas (such as alcohol) and can be quantified into a % concentration.

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>
   a. *Precision/Reproducibility:*
      This device was not tested by the National Highway Traffic Safety Administration (NHTSA). The sponsor performed their own testing and collected performance data using the NHTSA requirements for precision and accuracy as a guide. These requirements (referred to as Model Specifications) consist of 20 trials at a Blood Alcohol Concentration (BAC) of 0.008, 20 trials at a BAC of 0.032, and 20 trials at a BAC of 0.000. Blood Alcohol Concentrations are simulated in breath by a Breath Alcohol Sample Simulator (BASS), which provides an alcohol-in-air test sample with known alcohol

concentrations, flow rate, and air composition. The acceptance criteria for the Model Specifications are: not more than one negative result at 0.032 BAC, not more than one positive result at 0.008 BAC, and not more than one negative greater than zero and no positives at 0.000 BAC. NOTE: for the purposes of this study, a BAC of 0.020 is used to distinguish a positive from a negative result. The BACKTRACK™ Breathalyzer Digital Alcohol Detector device had no negatives at 0.032 BAC, no positives at 0.008 BAC, and no positives at 0.000 BAC.

b. *Linearity/assay reportable range:*
This device will report concentrations from 0.000 to 0.400%. However, DOT/NHTSA Model Specifications require accuracy and precision testing at concentrations of 0.008 and 0.032 only; therefore true linearity was not evaluated. This device demonstrated acceptable performance according to the Model Specifications as described above.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
This device is traceable to a commercially available certified alcohol reference solution at a concentration of 0.06 % BAC. This solution is used to calibrate the devices during manufacture.

d. *Detection limit:*
The DOT/NHTSA Model Specifications do not specifically address the detection limit of breath alcohol devices. However, the devices must be tested at a BAC of zero (blank reading) to assess the possibility of false positives. This consists of 20 trials under normal laboratory conditions using fluorescent light at a BAC of 0.000. Non-alcoholic human breath is to be used as the sample. For devices capable of providing a reading of greater than 0.000 BAC and less than 0.020 BAC, the acceptance criterion is: not more than one such result. The BACKTRACK™ Breathalyzer Digital Alcohol Detector had no false positives in this trial.

e. *Analytical specificity:*
The DOT/NHTSA Model Specifications require testing with cigarette smoke to assess any possible interference. Five trials are required at 0.000 BAC. An alcohol-free individual who smokes cigarettes is appropriate for this trial. The subject is asked to smoke approximately one half of a cigarette. Within one minute after smoking, or after a waiting period specified in the manufacturer's instructions*, the subject performs the breath alcohol test according to the manufacturer's instructions. The subject is then asked to smoke another inhalation and repeat the test to produce a total of five trials. The acceptance criterion for this trial is: no positive results. The BACKTRACK™ Breathalyzer Digital Alcohol Detector had no positive results.

*Manufacturer's labeling instructs the user to wait 20 minutes after smoking, eating, or drinking before taking a reading.

f. Temperature:

The DOT/NHTSA Model Specifications require testing at 10 and 40^{o} C to assess any possible effects of temperature.
At 10^{o} C, 20 trials are required at 0.008 BAC and 20 trials are required at 0.032 BAC. Acceptance criteria are: not more than one positive result at 0.008 BAC, and not more than one non-positive result at 0.032 BAC. The BACKTRACK™ Breathalyzer Digital Alcohol Detector had no positive results at 0.008 BAC and no non-positive results at 0.032 BAC.
At 40^{o} C, the requirements are identical. In this study the BACKTRACK™ Breathalyzer Digital Alcohol Detector had no positive results at 0.008 BAC and no non-positive results at 0.032 BAC.

g. Vibration:
The DOT/NHTSA Model Specifications require vibration testing to assess any possible vibrational effects.

Twenty trials are required at 0.008 BAC and 0.032 BAC. Acceptance criteria are: not more than one positive result at 0.008 BAC, and not more than one non-positive result at 0.032 BAC. The BACKTRACK™ Breathalyzer Digital Alcohol Detector had no positive results at 0.008 BAC and no non-positive results at 0.032 BAC.

h. Assay cutoff:
For the purposes of DOT performance testing, a BAC cutoff of 0.020 was used to distinguish positive from negative samples.
As of June 7, 2004, 49 states, along with the District of Columbia and Puerto Rico, have adopted .08 BAC as the legal level of intoxication in their state. Only Delaware remains at .10 BAC as the legally established level for drunk driving.
In their labeling, the sponsor states that driving skills *may* be impaired at a BAC of 0.04 - 0.06 and are *always* impaired at a BAC of 0.07 - 0.09.

2. <u>Comparison studies:</u>
   a. Method comparison with predicate device:
   The accuracy of this device is addressed in the precision section above. In addition, the sponsor conducted a consumer study comparing the BACKTRACK™ Breathalyzer Digital Alcohol Detector to a professional breath alcohol device. The purpose of the study was to determine if consumers could correctly use and interpret the device using only the supplied User's Manual, and to compare the results to the professional device. There were 85 paired comparisons, and the volunteers ranged in age from 21 to 60 years of age. Each participant took their own breath alcohol reading with the BACKTRACK™ Breathalyzer Digital Alcohol Detector and recorded the result. Immediately afterward, the participants were administered a breath

alcohol test using a Lifeloc Model FC-10 operated by a trained individual. The breath alcohol concentrations ranged from a BAC of 0.000 to 0.136 (by the professional device). Linear regression analysis of the data yielded a slope of 0.90491, a y-intercept of 0.00383, and a correlation coefficient of 0.904. After the study, participants were asked questions about ease of use and interpretation. The results are presented below:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
I am interested in buying this device	0	0	4	32	49
I found the device easy to use	0	1	3	32	49
I found the instructions clearly written	0	0	0	35	50
I understood the results	0	0	0	35	50

b. Matrix comparison:
Not applicable. This device is intended for one sample matrix only.

3. Clinical studies:
   a. Clinical Sensitivity:
   Not applicable.

   b. Clinical specificity:
   Not applicable.

   c. Other clinical supportive data (when a. and b. are not applicable):
   Not applicable.

4. Clinical cut-off:
   Not applicable.

5. Expected values/Reference range:
   Using these types of devices, alcohol is not detectable in the breath of persons who have not ingested alcohol.

N. Instrument Name:

BACKTRACK™ Breathalyzer Digital Alcohol Detector

O. System Descriptions:

1. Modes of Operation:
   Manually the user presses and holds the power button for one full second. After powering on, the unit will count down from 50 to zero. This countdown takes approximately 10 seconds. When the countdown approaches 10, the user is instructed to begin to inhale a deep breath. When the countdown reaches zero, the unit will flash "blow" and "0". The user exhales through the dual-flow breath chamber for five seconds while holding it 1/2 inch (13 mm) away from the mouth. When finished taking a breath sample, the BACTRACK will circle the outer LCD fields for three seconds while analyzing the breath sample. Once the BACTRACK has analyzed the breath sample, the estimated BAC (Blood alcohol content) value is displayed. The test result will be displayed for 10 seconds. Then the test result will blink for another 10 seconds before shutting off.

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes X or No _____

3. Specimen Identification:

   There is no mechanism to identify the specimen.

4. Specimen Sampling and Handling:

   The user obtains a breath sample by exhaling into the device.

5. Calibration:

   The device is calibrated at the factory. The instrument keeps track of the number of tests that have been performed. In the labeling users are instructed to have the device recalibrated after 300 tests have been performed. For recalibration, the user ships the device back to the manufacturer.

6. Quality Control:
   Typically, for theses types of devices, there are no external quality control (QC) materials or electronic QC functions.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.